Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of alpha lipoic acid on sperm parameters, DNA integrity and oxidative stress in infertile men with increased level of sperm DNA damage

Protocol summary

Study aim
Effect of alpha lipoic acid (ALA) on sperm parameters, DNA and oxidative stress in infertile men with increased sperm DNA damage

Design
Previous studies have indicated that the level of oxidative stress in infertile people is significantly higher than fertile individuals, the outcomes are sperm DNA damage, decreased fertilization, pregnancy and live birth as well as increased abortion. Therefore, treatment with antioxidants can be considered as one of the effective methods for improving sperm parameters. ALA is a unique antioxidant that can dissolve in water and fat and can significantly reduce the level of oxidative stress in the cells. In this research, triple blind clinical trial was done for 2 groups of 40 people. placebo group used two 300mg cap and treatment group uses two 300mg alpha Lipoic acid cap for 3 months.

Settings and conduct
After selecting patients in Royan Research Institute, patients randomly divided into two groups: placebo and the group receiving ALA. in this research, triple blind clinical trial was done for 2 groups of 40 people. placebo group used two 300mg cap and treatment group uses two 300mg alpha Lipoic acid cap for 3 months. Before and after three months, the routine and functional parameters of sperm will be examined.

Participants/Inclusion and exclusion criteria
Infertile men with normal sperm parameters and high DNA damage Infertile men with abnormal sperm parameters and high DNA damage

Intervention groups
Placebo group usage two 300 mg Placebo Cap. per day and ALA treatment group usage two 300 mg Alpha Lipoic Acid Cap. per day

Main outcome variables
The routine sperm analysis and sperm functional tests includes DNA fragmentation and ROS

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190406043177N1**
Registration date: **2019-08-21, 1398/05/30**
Registration timing: **retrospective**

Last update: **2019-08-21, 1398/05/30**
Update count: **0**

Registration date
2019-08-21, 1398/05/30

Registrant information

Name
Masoud Habibi

Name of organization / entity

Country
Iran (Islamic Republic of)

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mhabibi@mrcjd.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-22, 1397/04/01

Expected recruitment end date
2019-07-23, 1398/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of alpha lipoic acid on sperm parameters, DNA integrity and oxidative stress in infertile men with increased level of sperm DNA damage

Public title
Effect of alpha lipoic acid on male infertility

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Infertile men with normal sperm parameters and high levels of DNA fragmentation (SCSA>30 , TUNEL>15)
Infertile men with abnormal sperm parameters and high levels of DNA fragmentation (SCSA>30 , TUNEL>15)

Exclusion criteria:
Varicocele Leukocytospermia cancer and chemotherapy cytotoxic medicine usage

Age
No age limit

Gender
Male

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Block Randomization

Blinding (investigator's opinion)
Triple blinded

Blinding description
The drug and placebo package was similar and was given to patients by the pharmacist according to the numbers in randomization. The patient himself did not have any information on the use of the medicine or the placebo. The laboratory expert and researcher only analyzed the samples by the numbers.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Royan Institute

Street address
Royan Institute, Hafez St., Banihashem St, Tehran

City
Tehran

Province
Tehran

Postal code
16655659911

Approval date
2019-01-16, 1397/10/26

Ethics committee reference number
IR.ACECR.ROYAN.AEC.1397.108

Health conditions studied

1

Description of health condition studied
Male Infertility

ICD-10 code
N46

ICD-10 code description
Male infertility

Primary outcomes

1

Description
DNA Damage

Timepoint
Before starting the intervention - after 3 month use of medicine or placebo

Method of measurement
Flow cytometry device. Fluorescence and optic microscope

2

Description
sperm motility

Timepoint
Before starting the intervention - after 3 month use of medicine or placebo

Method of measurement
CASA Device

3

Description
sperm morphology

Timepoint
Before starting the intervention - after 3 month use of medicine or placebo

Method of measurement

microscope

4

Description
sperm count
Timepoint
Before starting the intervention - after 3 month use of medicine or placebo
Method of measurement
neobar lam

5

Description
sperm vitality
Timepoint
Before starting the intervention - after 3 month use of medicine or placebo
Method of measurement
microscope

6

Description
Lipid peroxidation (MDA level)
Timepoint
Before starting the intervention - after 3 month use of medicine or placebo
Method of measurement
spectrophotometer

7

Description
Mitochondrial membrane potential
Timepoint
Before starting the intervention - after 3 month use of medicine or placebo
Method of measurement
Flow Cytometry device

8

Description
TAC
Timepoint
Before starting the intervention - after 3 month use of medicine or placebo
Method of measurement
ELISA Reader

9

Description
SOD
Timepoint
Before starting the intervention - after 3 month use of medicine or placebo
Method of measurement
ELISA Reader

10

Description
GPX
Timepoint
Before starting the intervention - after 3 month use of medicine or placebo
Method of measurement
ELISA Reader

11

Description
ROS
Timepoint
Before starting the intervention - after 3 month use of medicine or placebo
Method of measurement
Flow Cytometry device

12

Description
Chromatin evaluation
Timepoint
Before starting the intervention - after 3 month use of medicine or placebo
Method of measurement
Flow Cytometry device

Secondary outcomes

1

Description
Fertilization Rate
Timepoint
After Treatment
Method of measurement
Patient Flow up and Fertility Tests

Intervention groups

1

Description
Control group: 3 month usage of placebo
Category
Placebo

2

Description
Intervention group: 3 month usage of 2 Cap. 300 mg alpha lipoic acid Bd before Breakfast and Lunch
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Royan Institute

Full name of responsible person
Prof. Mohammad Hossein Nasr Esfahani

Street address
No.2, Hafez St., Banihashem St., Resalat Ave., Tehran, Iran

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ric@royaninstitute.org

Web page address
http://www.royaninstitute.org

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Royan Institute

Full name of responsible person
Dr. Abdolhossein Shahverdi

Street address
No.2, Hafez St., Banihashem St., Resalat Ave., Tehran, Iran

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shahverdi@royaninstitute.org

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Royan Institute

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Royan Institute

Full name of responsible person
Prof. Mohammad Hossein Nasr Esfahani

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Embryologist

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No.371, Allikhani Aleey, Mehr St., Salman Farsi Ave., Isfahan, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Iranian academic center for education culture and research

Full name of responsible person

Dr. Masoud Habibi

Position

PhD Candidate

Latest degree

Medical doctor

Other areas of specialty/work

Reproductive Biology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

A portion of the information, such as information on the main outcome or the like, can be shared.

When the data will become available and for how long

Starting access period from 1399

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

According to the supervisor

From where data/document is obtainable

supervisor

What processes are involved for a request to access data/document

Individuals refer their application to the supervisor of the project and after reviewing their application, that would be sent them.

Comments